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June 20, 2000

Jere W. Glover  
Chief Counsel for Advocacy  
Small Business Administration  
409 3<sup>rd</sup> St. S.W.  
Washington D.C. 20416

Dear Mr. Glover:

I am writing as counsel to the Ephedra Committee of the American Herbal Products Association, and as a partner in a law firm that specializes in Food and Drug regulatory matters, to thank the Office of Advocacy, and specifically Ms. Shawne C. McGibbon and Ms. Mary K. Ryan, for providing essential and timely help to small businesses that sell dietary supplements. Without the help of the Small Business Administration (SBA), the earnings of hundreds of thousands of direct sales distributors of supplement products and other small businesses would have been substantially reduced by irrational government regulation. Further, the actions of the SBA have, in the view of knowledgeable experts in the weight loss area, resulted in an enormous public health benefit to consumers.

In 1997, the Food and Drug Administration (FDA) published a proposed regulation that would have essentially eliminated dietary supplements containing ephedra from the market. The products are safely used as effective weight loss aids and for energy by millions of Americans. The SBA Office of Advocacy submitted to FDA extensive and highly critical comments on this proposal. The SBA comments supported the comments of small businesses and other representatives of industry and helped to establish not only that FDA had failed to accurately assess the economic impact of the proposal on small businesses, but also that the proposed regulation appeared on its face to have no valid scientific basis.

Jere W. Glover  
June 20, 2000  
Page 2

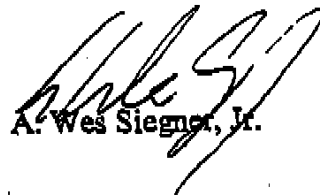
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As a direct result of SBA's comments, Congress took a strong interest in FDA's proposal and requested the General Accounting Office (GAO) to audit the proposed regulation. In 1999, the GAO published a highly critical report and recommended that FDA not proceed with the rulemaking as proposed because of the lack of any rational scientific basis for the proposed rule.

FDA withdrew the most controversial portions of the proposed regulation on April 3, 2000. This is an astounding and unprecedented turnaround that would not have occurred without the SBA's help. Last year, according to a recent Arthur Anderson survey, well over three billion servings of ephedra supplements were sold, benefiting consumers and providing needed income to hundreds of thousands of small businesses. New research that has been conducted since 1997, some of which will be published this year, further establishes that industry's, consumers' and the SBA's skepticism about FDA's proposal was well-founded — ephedra products, when responsibly marketed and consumed, are safe and useful as weight loss aids, and are one of a very few but very important tools in the fight against excess weight in America.

As a result of the support the Office of Advocacy has provided, I am now convinced the SBA is an essential watchdog to prevent ill-conceived FDA regulation. I am confident that Congress will recognize the need for a strong SBA to help small businesses protect themselves from unnecessary and damaging regulations.

Sincerely,



A. Wes Siegner, Jr.

AWS/eal